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**VIA FEDERAL EXPRESS**

Docket Number 95S-0158 (BB IND # 10719)  
Dockets Management Branch  
Food and Drug Administration  
Room 1061, Mail Stop HFA-305  
5630 Fisher's Lane  
Rockville, MD 20852

February 9, 2005

**RE: BB IND 10719, POLY-SFH-P INJECTION [Polymerized Human Hemoglobin  
(Pyridoxylated), PolyHeme®]  
Protocol RTBSE-11-(N): Publicly Disclosed Information**

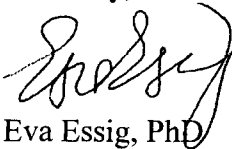
Dear Sir:

Please refer to our submission of Public Disclosure information for the **Denver Health**, Denver, CO site on January 8, 2004. Attached we submit to the docket the Press Release and Questions and Answers document which are posted on the Denver Health website ([www.denverhealth.org](http://www.denverhealth.org)).

Please also refer to our submission of Public Disclosure information for the **MetroHealth Medical Center**, Cleveland, OH on April 7, 2004. We now provide the August 6, 2003 and August 28, 2003 community meeting presentations.

A copy of this submission is being submitted to Northfield BB IND # 10719 as well.

Sincerely,



Eva Essig, PhD  
Vice President of Regulatory Affairs and Quality

Attachment

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